UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

September 25, 2007

MEMORANDUM

SUBJECT: Review of "*Determination of Removal Efficiency of Pyrethrin (PY) and Piperonyl Butoxide (PBO) From Vinyl Flooring Sections Using DSS and IPA*"

FROM: Dana Vogel, Senior Scientist
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TO: Cathryn O'Connell
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DP Barcode: 336757
PC Code: 069001
MRID Number: 46188612

Attached is a review of the MRID 46188612 "*Determination of Removal Efficiency of Pyrethrin (PY) and Piperonyl Butoxide (PBO) From Vinyl Flooring Sections Using DSS and IPA*" submitted by the Non-Dietary Exposure Task Force. The purpose of the study was to determine the total amount of pyrethrin (PY) and piperonyl butoxide (PBO) residues that can be removed from a treated vinyl flooring, following application of a measured amount of a typical pre-fill batch formulation containing 0.774% and 1.63% PY and PBO, respectively. The primary review for this study was conducted by Versar, Inc. A secondary review was conducted by the Health Effects Division (HED).

Results

The desired deposition rate of the test material onto the vinyl flooring was 3.96 $\mu g/cm^2$ for PY

and 7.87 μg/cm^2 for PBO.[1] Total deposition was measured using deposition coupons, which were collected after application of the test material, followed by a drying period. The removal of the test substance was conducted about 3.5 hours following application. A 10 x 10 cm area of each flooring section was wiped with two dressing sponges wetted with dioctyl sodium sulfosuccinate (DSS), followed by two dressing sponges wetted with isopropyl alcohol (IPA). The dressing sponges were extracted and then analyzed using GC/MS.

The total amount of residues removed with dressing sponges wetted with DSS and IPA were calculated by the study author for all four vinyl flooring sections. According to the study author, residues removed by DSS averaged 39.9 ± 15.5 µg/sample for PYI, 72.1 ± 28.1 µg/sample for PY, and 113.0 ± 39.0 µg/sample for PBO; and residues removed by IPA averaged 16.4 ± 4.25 µg/sample for PYI, 29.6 ± 7.68 µg/sample for PY, and 56.7 ± 14.3 µg/sample for PBO. Residues were corrected for samples that had field fortification recoveries below 90%. Mean corrected residues removed by DSS for PYI, PY and PBO were 52.3 ± 20.4 µg/sample, 94.6 ± 36.9 µg/sample, and 140.2 ± 48.3 µg/sample, respectively. Mean corrected residues removed by IPA for PYI, PY and PBO were 21.5 ± 5.6 µg/sample, 38.9 ± 10.1 µg/sample, and 70.0 ± 17.7 µg/sample, respectively.

The percent of the applied compound that could be removed from the vinyl flooring was calculated as a ratio of the µg of compound in the wipes divided by the mean deposition rate on the alpha cellulose coupons. The uncorrected residue deposited on the coupons was reported to be 4.66 μg/cm^2 for PY and 10.2 μg/cm^2 for PBO. When corrected for the field fortification recoveries, the coupon residues averaged 6.75 ± 1.43 µg/cm^2 for PY and 16.95 ± 3.12 µg/cm^2 for PBO. The percent of application reported by the study author using the uncorrected coupon residues removed by DSS were 20.3% for PY and 13.7% for PBO; uncorrected coupon residues removed by IPA were 8.34% for PY and 6.87% for PBO. The percent of application removed by DSS for PY and PBO, using the corrected coupon residues, were 14.01% and 8.27%, respectively. The percent of application removed by IPA for PY and PBO, using the corrected coupon residues were 5.47% and 4.13%, respectively.

Conclusions

The primary review for this study was conducted by Versar, Inc. A secondary review was conducted by the Health Effects Division (HED). The protocol provided with the study along with OPPTS Series 875 Part B, Guideline 875.2300: Indoor Surface Residue Dissipation, Postapplication and Part C Guidelines were used to review the study. Overall, both the performance of this study and the data generated in this study conformed to the criteria set forth in the protocol and guidelines. HED believes the data within this study is of high quality and valid for risk assessment purposes.

[1] The vinyl flooring sections used in this study were obtained from a previous sprayboom application that generated excess sections for another study.

Versar inc.

Reviewers: Traci Brody/Linda Phillips **Date: March 9, 2004**

STUDY TYPE: Active Transfer; Vinyl

TEST MATERIAL: Pyrethrin and Piperonyl Butoxide; pre-fill batch formulation (similar to that for an indoor fogger formulation)

SYNONYMS: Pyrethrin (PY) and Piperonyl Butoxide (PBO)

CITATION:

Author(s):	Sami Selim, Ph.D.
Study Director(s):	Robert E. Rogers, Ph.D, D.A.B.T., P.Biol.
Title:	*Determination of Removal Efficiency of Pyrethrin (PY) and Piperonyl Butoxide (PBO) From Vinyl Flooring Sections Using DSS and IPA*
Study Completion Date:	August 24, 2002
Testing Facility:	Toxcon Health Sciences Research Centre Inc. 9607 - 41st Avenue Edmonton, Alberta Canada T6E 5XL
Analytical Facility:	Enviro-Test Laboratories/XENOS Division Unit 13 - 210 Colonnade Road Nepean, Ontario Canada K2E 7L5
Identifying Codes:	Toxcon Project Id: 00-037-PY01 Xenos Project No.: XEN00-36

SPONSOR: on-Dietary Exposure Task Force

EXECUTIVE SUMMARY:

This report reviews "*Determination of Removal Efficiency of Pyrethrin (PY) and Piperonyl Butoxide (PBO) From Vinyl Flooring Sections Using DSS and IPA*" submitted by the Non-Dietary Exposure Task Force. The purpose of the study was to determine the total amount of pyrethrin (PY) and piperonyl butoxide (PBO) residues that can be removed from a treated vinyl flooring, following application of a measured amount of a typical pre-fill batch formulation containing 0.774% and 1.63% PY and PBO, respectively.

Four vinyl flooring sections were obtained from a previous sprayboom application that generated excess sections for another study. The desired deposition rate of the test material onto the vinyl flooring was 3.96 $\mu g/cm^2$ for PY and 7.87 $\mu g/cm^2$ for PBO. Total deposition was measured using deposition coupons, which were collected after application of the test material, followed by a drying period. The removal of the test substance was conducted about 3.5 hours following application. A 10 x 10 cm area of each flooring section was wiped with two dressing sponges wetted with dioctyl sodium sulfosuccinate (DSS), followed by two dressing sponges wetted with isopropyl alcohol (IPA). The dressing sponges were extracted and then analyzed using GC/MS.

The total amount of residues removed with dressing sponges wetted with DSS and IPA were calculated by the study author for all four vinyl flooring sections. According to the study author, residues removed by DSS averaged 39.9 ± 15.5 µg/sample for PYI, 72.1 ± 28.1 µg/sample for PY, and 113.0 ± 39.0 µg/sample for PBO; and residues removed by IPA averaged 16.4 ± 4.25 µg/sample for PYI, 29.6 ± 7.68 µg/sample for PY, and 56.7 ± 14.3 µg/sample for PBO. Versar corrected residues for field fortification recoveries that were below 90%. Mean corrected residues removed by DSS for PYI, PY and PBO were 52.3 ± 20.4 µg/sample, 94.6 ± 36.9 µg/sample, and 140.2 ± 48.3 µg/sample, respectively. Mean corrected residues removed by IPA for PYI, PY and PBO were 21.5 ± 5.6 µg/sample, 38.9 ±

10.1 µg/sample, and 70.0 ± 17.7 µg/sample, respectively.

The percent of the applied compound that could be removed from the vinyl flooring was calculated as a ratio of the µg of compound in the wipes divided by the mean deposition rate on the alpha cellulose coupons. The uncorrected residue deposited on the coupons was reported to be 4.66 $\mu g/cm^2$ for PY and 10.2 $\mu g/cm^2$ for PBO. When corrected for the field fortification recoveries, the coupon residues averaged 6.75 ± 1.43 $\mu g/cm^2$ for PY and 16.95 ± 3.12 $\mu g/cm^2$ for PBO. The percent of application reported by the study author using the uncorrected coupon residues removed by DSS were 20.3% for PY and 13.7% for PBO; uncorrected coupon residues removed by IPA were 8.34% for PY and 6.87% for PBO. The percent of application removed by DSS for PY and PBO, as calculated by Versar using the corrected coupon residues, were 14.01% and 8.27%, respectively. The percent of application removed by IPA for PY and PBO, as calculated by Versar using the corrected coupon residues were 5.47% and 4.13%, respectively.

The protocol provided with the study along with OPPTS Series 875 Part B, Guideline 875.2300: Indoor Surface Residue Dissipation, Postapplication and Part C Guidelines were used to review the study. Overall, the majority of the procedures performed and the quality of the data generated in this study conformed to the criteria set forth in the protocol and guidelines. However, certain issues of concern were noted:

- A specific application rate was not provided in the Study Report. Application was based on a target deposition rate determined in another study.
- The test product was not identified and no label was provided.
- None of the test conditions (temperature, barometric pressure, ventilation) were reported.
- Calibration procedures for the application equipment were not provided in the Study Report.
- The blank deposition coupon sample results were not provided in the Study Report.
- The study author did not correct the PY residue data for the field fortification recovery, which was below 90%.
- Discrepancies were noted regarding the batch number of formulated product used and the percent of PY and PBO in the formulation. The Study Report states that batch LPB47000b was used and that it contained 0.770% PY and 1.64% PBO, but the Study Protocol and Analytical Phase Report say that batch LPB4700a was used and that it contained 0.770% PY and 1.64% PBO. The protocol amendment says that batch LPB47000b was used, but that it contained 0.774% PY and 1.63% PBO. The Certificate of Analysis was for batch LPB47000b and shows percentages of 0.774% for PY and 1.63% for PBO. Note also that Page 49 of the Study Report states that "Treated samples were generated using a different formulated product "[from the fortified samples]." "The percent composition of the product used was [0.774% PY] and 1.63% PBO".

COMPLIANCE:
Signed and dated GLP, and Data Confidentiality statements were provided. The Study Report noted that the study was not performed according to the U.S. EPA FIFRA Good Laboratory Practice Regulations currently in effect (40 CFR, Part 160), however, all data collection and study conduct was performed "in the spirit of GLP." The data generated at Toxcon was not audited and the data and Analytical Report generated at Xenos were reviewed by Xenos' Quality Assurance representative. A Quality Assurance statement was provided us part of the Analytical Phase Report which was included as an Appendix.

GUIDELINE OR PROTOCOL FOLLOWED:
The study was reviewed using OPPTS Test Guidelines Series 875, Occupational and Residential Exposure Test Guidelines, Group B: 875.2300. The study was conducted following Xenos and Toxcon Standard Operating Procedures and the protocol of the Non-Dietary Exposure Task Force (Toxcon Protocol No. 00-037-PY01). The study protocol was approved by study management on September 5, 2000.

I. MATERIALS AND METHODS

A. Materials:

1. Test Material:

Formulation:	An unidentified pre-fill batch fogger formulation similar to that for an indoor fogger; developed by McLaughlin Gormley King Company (MGK); contains 0.774% PY (wt/wt) and 1.63% PBO (wt/wt) as the active ingredients.
Lot/Batch # formulation:	LPB47000b (as per protocol amendment)
Formulation guarantee:	Certificate of analysis provided
CAS #(s):	Pyrethrin (PY): 8003-34-7
	PBO: 51-03-6
Other Relevant Information:	Toxcon ID No.: PY01T006

2. Relevance of Test Material to Proposed Formulation(s):

Pyrethrin and piperonyl butoxide are active ingredients used in formulated consumer products intended for use in residential buildings. The product used was a pre-fill batch formulation similar to that for an indoor fogger formulation developed by McLaughlin Gormley King Company (MGK). The name and label for the test product was not provided with the study.

B. Study Design:

There was one amendment to and three deviations from the study protocol. The amendment was the following: the test substance batch used for the experiment was Batch #LPB47000b with 0.774% PY and 1.63% PBO. The deviations from the protocol were as follows: 1) the recoveries from laboratory fortified samples were not in the 70-120% range for the fortified dressing sponge sample DS-F1; 2) the peak area exceeded the area of the largest standard injection by more than 10% for PYI in sample DS-F2; and 3) set X003602a demonstrated a R^2 value for PYI of 0.9787.

1. Site Description:

Test locations:	Not provided.
Meteorological Data:	Not provided.
Ventilation/Air-Filtration:	Not provided.

2. Surface(s) Monitored:

Room(s) Monitored:	Not provided.
Room Size(s):	Not provided.
Types of Surface(s):	Vinyl flooring
Surface Characteristics:	Four vinyl flooring sections were obtained from a previous sprayboom application that generated excess sections.

Areas sprayed and sampled: A 10 x 10 cm area of each vinyl flooring section was wiped with four dressing sponges to determine the amount of compound that is transferred from the hand to mouth.

Other products used: N/A

3. Physical State of Formulation as Applied : Fogger

4. Application Rates and Regimes:

Application Equipment: Sprayboom

Application Regime: Not provided. The application was completed in another study.

Application rate(s): An application rate was not provided in the Study Report. Application was based on the desired deposition rate of the test material onto the vinyl flooring. For PY, the desired deposition rate was 3.96 μg/cm^2 and for PBO, the desired deposition rate was 7.87 μg/cm^2. Target deposition rates were based on results of indoor PY and PBO total release fogger deposition studies.

Equipment Calibration Procedures: The Study Report states that a calibrated sprayboom was used in the study, but calibration procedures were not provided. It is not certain if the equipment used in this study was consistent with the proposed use for this product. A label was not provided with the study. Therefore, the label recommended application method is not known.

Was total deposition measured? Total deposition was measured using alpha cellulose deposition coupons. Analysis of PYI and PBO in the alpha cellulose deposition coupons was conducted according to Xenos' analytical method XAM-60 and the associated SOPs defined by Xenos.

D. Sampling:

Surface Areas Sampled: A 10 x 10 cm section of the vinyl flooring sections were sampled.

Replicates per sampling interval: Four vinyl flooring sections were sampled.

Number of sampling intervals: There was one sampling interval that occurred about 3.5 hours after application (i.e., 3 hours deposition period and 30 minute drying period).

Method and Equipment: Residue deposition and transfer were determined using deposition coupons, and four 4" x 4" 6-ply dressing sponges and wetted with about 5 mL of either DSS or IPA.

Sampling Procedure(s) :

Deposition coupons - Details on the deposition coupon sampling was not provided.

Dressing sponge residues- A template consisting of an untreated vinyl section of the same size as the treated vinyl section was prepared. A 10 cm x 10 cm section in the middle of the template vinyl section was cut out. The template vinyl section was placed on top of the treated vinyl section. The removal of the formulation from the treated surface consisted of wiping the 10 x 10 cm area with 4" x 4" 6-ply dressing sponges. The vinyl surface was first swabbed with two dressing sponges that had been treated with DSS and then with two dressing

sponges wetted with IPA.

3. Sample Handling and Storage:
The dressing sponges were placed in glass jars and stored in the dark at less than -10 C until being shipped to the analytical laboratory. Sample storage and shipment were conducted according to Toxcon Nos. G-022 *Storage of Test Samples and Analytical Extracts* and G-028 *Test Sample Distribution to a Contract Laboratory*. Samples were shipped to the analytical laboratory by airfreight with priority overnight delivery. Samples were shipped in an insulated cooler with dry ice.

IV. ANALYTICAL METHODOLOGIES

A. Extraction method:

Dressing sponges: Extraction was performed by sonication and mechanical shaking of the dressing sponges at room temperature with ethyl acetate. One extraction was performed and the ethyl acetate was taken to dryness by rotary evaporation. Two clean-up steps were required for the sponges, including the use of a Discovery™ polyamide SPE cartridge and an Isolute silica SPE cartridge. All sample extracts were taken to dryness and made up to an appropriate volume in toluene.

B. Detection methods:
A Varian Saturn 2000 GC/MS system was used consisting of a Model 8200 autosampler, 1079 SPI injector, and a 3800 GC connected to the MS ion trap detector. The system was operated in the EI/SIM mode. See Table 1 for details on the GC conditions.

Table 1. Gas Chromatographic Conditions

GC Column	DB-5, ~15 m x 0.25 mm ID, 0.25 μm film
Temperatures	Inlet: Initial - 120°C (hold 0.15 min) Prog 1 - 120-250°C @ 200°C/min (hold 10 min) Column: Initial - 90°C (hold 1.5 min) Prog 1 - 90-160°C @ 30°C/min Prog 2 - 160-175°C @ 1.8°C/min Prog 3 - 175-200°C @ 2.0°C/min Prog 4 - 200-320°C @ 50°C/min (hold 15 min) Transfer line: 280°C
Carrier Gas Flow Rate	~1.3 mL/min (constant)
Mass Spectrometer Interface	direct capillary interface
GC/MS Mode	EI/SIM
Injector Split	0 min, split ON, split ratio: 10 0.25 min, split OFF 2.00 min, split ON, split ratio: 100
Injection Volume	5.0 μL direct injection
Rate	0.4 μL/sec
Quantitating Mass Ions	PYI (all esters): m/z 123 ion PBO: m/z 193 ion

Approximate Retention Times	C-I ~ 17 min J-I ~ 20 min P-I ~ 21 min PBO ~ 23 min

D. Method Validation:

The analytical methods were validated in a previous study. The Study Report states that validation data for the limit of quantitation (LOQ) was taken from Xenos report XEN00-14. LOQs are reported for PYI, PY and PBO (see Table 2).

Table 2. Validated LOQs

Matrix	Formulation	PYI	PY	PBO
Dressing Sponges	200 µg	0.882 µg	1.58 µg	3.20 µg

Instrument performance and calibration: Calibration solutions were prepared from the formulation by dilution in toluene. A total of 5 concentrations were used to calibrate the system: 0.010, 0.020, 0.040, 0.075, and 0.100 µg/µL. The GC/MS response was determined using the prepared calibration standards to perform a linear regression analysis.

E. Quality Control:

Lab Recovery: To obtain recovery and method performance data, concurrent laboratory control dressing sponge samples were fortified with the formulated product. Samples were fortified at the LOQ, 2x the LOQ, 5x the LOQ, and 500 the LOQ. Results from the laboratory fortified samples are summarized in Table 3. The recovery of the low level spike for PYI was 131.6% versus 78.0% at the high level. The recovery of the low level spike for PBO was 129.6% versus 87.1% at the high level. Overall average recoveries were 103.6 ± 24.6% for PYI and 102.7 ± 18.7% for PBO.

Table 3. Summary of Concurrent Laboratory Fortification Recoveries

Matrix	Fortification Level (µg)[1]		Measured Residue (µg/sample)		Percent Recovery (%)		Overall Average Recovery (%)		Std. Dev.		% RSD	
	PYI	PBO	PYI	PBO	PYI	PBO	PYI	PBO	PYI	PBO	PYI	PBO
Dressing sponge	0.836	3.28	1.10	4.25	131.6	129.6	103.6	102.7	24.6	18.7	23.8	18.2
	1.67	6.56	1.48	6.17	88.6	94.1						
	4.18	16.4	4.85	16.4	116.0	100.0						
	418	1640	326	1428	78.0	87.1						

1 Fortification levels were at 1x, 2x, 5x and 500x the LOQ.

Field Fortification: Samples of the dressing sponges, wetted with either DSS or IPA, were fortified with an amount of stock solution equivalent to 250 µg (75x LOQ) of PBO. Duplicate samples were prepared and exposed for the same time and under the same conditions as the test samples. These samples were stored and analyzed with the test samples. Field

fortification results are summarized in Table 4. Overall average recoveries were 76.2 ± 2.40% for PYI and 80.9 ± 1.92% for PBO. The Study Report states that field fortification samples of the alpha cellulose coupons were also prepared, but the results are provided in another study (Toxcon Study 00-035-PY01).

Table 4. Summary of Field Fortification Recoveries.

Matrix	Fortification Level (µg)[1]		Measured Residue (µg/sample)		Percent Recovery (%)		Overall Average Recovery (%)		Std. Dev.		% RSD	
	PYI	PBO	PYI	PBO	PYI	PBO	PYI	PBO	PYI	PBO	PYI	PBO
Dressing sponge	64.0	251	50.4	201	78.8	80.1	76.2	80.9	2.40	1.92	3.15	2.38
			49.1	199	76.7	79.3						
			46.7	202	73.0	80.5						
			48.9	210	76.4	83.7						

1 Fortification level was approximately 75x the LOQ.

Control Samples: Each analytical set included one laboratory control. All concurrent laboratory control samples for the dressing sponges had detectable residue levels that were below the limit of quantification.

Storage Stability: The field fortified samples were analyzed after a period of 19 days of frozen storage. The Study Report stated that this confirmed the stability of the residues over this time period.

V. RESULTS

Versar corrected residue data for field fortification recoveries below 90%. The study author did not correct for field fortification recoveries. Residues were reported for both PYI and PBO, as well as PY, which is total PY calculated from the PYI data by using a conversion factor (1.808) derived from the percentages of total PYs and PYI in the formulated product.

A. Alpha Cellulose and Deposition of Formulation:

The Study Report states that the results of the analysis of the deposition coupons were reported in a different report (Toxcon Study 00-035-PY01). The overall mean for PY is reported as 4.66 ± 0.99 µg/cm^2 and for PBO as 10.2 ± 1.87 µg/cm^2. The achieved deposition rate is reported to be 118% of the target deposition rate for PY and 130% of the target deposition rate for PBO. Versar examined the coupon residue data reported in Toxcon Study 00-035-PY01 and found that the field fortification recoveries for the deposition coupons were below 90%. Recoveries averaged 69.1% for PY and 60.1% for PBO. Therefore, Versar corrected the deposition coupon residue data. Corrected residues were calculated by Versar to be 6.75 ± 1.43 µg/cm^2 for PY and 16.95 ± 3.12 µg/cm^2 for PBO. The achieved deposition rate using these values is 170% for PY and 215% for PBO. The corrected deposition values were used by Versar in calculating the percent of PY and PBO residues transferred from the vinyl flooring to the dressing sponges.

B. Dressing Sponge Wipe Residue:

The total amount of residues removed from the dressing sponges by DSS and IPA were calculated by the study author for all four vinyl flooring sections. Residues are reported for PYI (three pyrethrin esters), PY and PBO. According to the study author, residues removed by DSS averaged 39.9 ± 15.5 µg/sample for PYI, 72.1 ± 28.1 µg/sample, and 113.0 ± 39.0 µg/sample for PBO; and residues removed by IPA averaged 16.4 ± 4.25 µg/sample for PYI, 29.6 ± 7.68 µg/sample for PY, and 56.7 ± 14.3 µg/sample for PBO. Versar corrected PYI and PBO residues for field fortification recoveries of 76.2% and 80.9%, respectively. Mean corrected residues removed by DSS for

PYI, PY and PBO were 52.3 ± 20.4 µg/sample, 94.6 ± 36.9 µg/sample, and 140.2 ± 48.3 µg/sample, respectively. Mean corrected residues removed by IPA for PYI, PY and PBO were 21.5 ± 5.6 µg/sample, 38.9 ± 10.1 µg/sample, and 70.0 ± 17.7 µg/sample, respectively.

The percent of the applied compound that could be removed from the vinyl flooring was calculated as a ratio of the µg of compound in the wipes divided by the mean deposition rate on the alpha cellulose coupons. The uncorrected residue deposited on the coupons was reported to be 4.66 $\mu g/cm^2$ for PY and 10.2 $\mu g/cm^2$ for PBO. When corrected for the field fortification recoveries, the coupon residues averaged 6.75 ± 1.43 $\mu g/cm^2$ for PY and 16.95 ± 3.12 $\mu g/cm^2$ for PBO. The percent of application removed by DSS, as reported by the study author using the uncorrected coupon residues, was 15.5% for PY and 11.1% for PBO; uncorrected coupon residues removed by IPA were 6.4% for PY and 5.6% for PBO. The percent of application for PY and PBO calculated by Versar using the corrected coupon residues, removed by DSS were 14.01% and 8.27%, respectively. The percent of application for PY and PBO calculated by Versar using the corrected coupon residues removed by IPA were 5.47% and 4.13%, respectively.

VI. CONCLUSION

The total amount of residues removed from dressing sponges by DSS and IPA were calculated by the study author for four vinyl flooring sections. Residues removed by DSS averaged 39.9 ± 15.5 µg/sample for PYI, 72.1 ± 28.1 µg/sample, and 113.0 ± 39.0 µg/sample for PBO; and residues removed by IPA averaged 16.4 ± 4.25 µg/sample for PYI, 29.6 ± 7.68 µg/sample for PY, and 56.7 ± 14.3 µg/sample for PBO.

Versar also calculated residues based on the data provided for dressing sponges. Mean corrected residues removed by DSS for PYI, PY and PBO were 52.3 ± 20.4 µg/sample, 94.6 ± 36.9 µg/sample, and 140.2 ± 48.3 µg/sample, respectively. Mean corrected residues removed by IPA for PYI, PY and PBO were 21.5 ± 5.6 µg/sample, 38.9 ± 10.1 µg/sample, and 70.0 ± 17.7 µg/sample, respectively.

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LIMITATIONS OF THE STUDY:

The protocol provided with the study along with OPPTS Series 875 Part B, Guideline 875.2300: Indoor Surface Residue Dissipation, Postapplication and Part C Guidelines were used to review the study. Overall, the majority of the procedures performed and the quality of the data generated in this study conformed to the criteria set forth in the protocol and guidelines. However, certain issues of concern were noted:

- A specific application rate was not provided in the Study Report. Application was based on a target deposition rate determined in another study.
- The test product was not identified and no label was provided.
- None of the test conditions (temperature, barometric pressure, ventilation) were reported.
- Calibration procedures for the application equipment were not provided in the Study Report.
- The blank deposition coupon sample results were not provided in the Study Report.
- The study author did not correct the PY residue data for the field fortification recovery, which was below

90%.

- Discrepancies were noted regarding the batch number of formulated product used and the percent of PY and PBO in the formulation. The Study Report states that batch LPB47000b was used and that it contained 0.770% PY and 1.64% PBO, but the Study Protocol and Analytical Phase Report say that batch LPB4700a was used and that it contained 0.770% PY and 1.64% PBO. The protocol amendment says that batch LPB47000b was used, but that it contained 0.774% PY and 1.63% PBO. The Certificate of Analysis was for batch LPB47000b and shows percentages of 0.774% for PY and 1.63% for PBO. Note also that Page 49 of the Study Report states that "Treated samples were generated using a different formulated product "[from the fortified samples]." "The percent composition of the product used was [0.774%PY] and 1.63% PBO".

Table 5. Summary of PY and PBO Dressing Sponge Wipe Results on Vinyl Flooring

Replicate		Measured Residue (µg/sample)			Field Fortification Recovery		Corrected Residue (µg/sample)			Average Corrected Residue (µg/sample)			% of Application[c]		Average % of Application	
		PYI	PY[a]	PBO	PYI	PBO	PYI	PY[a]	PBO	PYI	PY[a]	PBO	PY	PBO	PY	PBO
DSS	RV1D	53.7	97.1	140	76.2	80.9	70.5	127.4	173.1	52.3 ± 20.4	94.6 ± 36.9	140.2 ± 48.3	18.9	10.2	14.01 ± 5.76	8.27 ± 2.85
	RV2D	40.0	72.3	115			52.5	94.9	142.2				14.1	8.4		
	RV3D	47.6	86.1	141			62.5	113.0	174.3				16.7	10.3		
	RV4D[b]	18.1	32.7	57.7			23.8	42.9	71.3				6.4	4.2		
IPA	RV1P	20.5	37.1	69.7			26.9	48.7	86.2	21.5 ± 5.6	38.9 ± 10.1	70.0 ± 17.7	7.2	5.1	5.47 ± 1.49	4.13 ± 1.04
	RV2P	18.3	33.1	63.2			24.0	43.4	78.1				6.4	4.6		
	RV3P	16.1	29.1	57.1			21.1	38.2	70.6				5.7	4.2		
	RV4P[b]	10.6	19.2	36.6			13.9	25.2	45.2				3.7	2.7		
													TOTAL		19.8	12.4

a PY is total PY calculated by using a conversion factor (1.808) derived from the percentages of total PYs and PYI in the formulated product.

b For sample 4, the PY and PBO residues in the DSS and IPA wipes are about half of those in the other 3 samples. Since this low residue is consistent in both the DSS and IPA wipes, the study author reported that it is very likely that the initial residue on the fourth vinyl flooring section was lower than the other sections.

c Calculated as the ratio of the amount of residue removed from vinyl tile in $\mu g/cm^2$ divided by the average residue found on the alpha cellulose coupons (4.66 $\mu g/cm^2$ for PY and 10.20 $\mu g/cm^2$ for PBO corrected to 6.75 $\mu g/cm^2$ for PY and 16.95 $\mu g/cm^2$ for PBO based on field fortification recovery data).